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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,973	02/26/2002	James S. Norris	14017-004002 /PSU 96-1566	8113
26161	7590	06/26/2006	EXAMINER EPPS FORD, JANET L	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			ART UNIT 1633	PAPER NUMBER

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,973

Applicant(s)

NORRIS ET AL.

Examiner

Janet L. Epps-Ford

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1,4,5,7,10,12,17,19-24,26,35,36 and 38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1,4,5,7,10,12,17,19-24,26,35,36 and 38 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4-03-06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 112

2. Claims 1, 4-5, 7, 10, 12, 17, 19-24, 26, and 35-36, and 38 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter and Written Description), for the reasons of record set forth in the prior Office Action.

3. Applicant's arguments filed 4-04-06 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the structure recited in the instant claims is fully disclosed in Applicant's specification. According to Applicants Page 36, lines 4-8 disclose lengthening the arms of cis-acting ribozymes of a pCLIP cassette. However, contrary to Applicant's assertions, this portion of the specification as filed, which incorporates the disclosures of US Serial No. 08/554,369 and PCT publication WO 98/24925 in their entirety, does not provide sufficient support for lengthening the arms of cis-acting ribozymes (to an undefined length) of a pCLIP cassette. First it is noted that the specification as filed describes Figure 2 of the specification as filed as the pCLIP ribozyme cassette (see page 9, lines 3-8):

Art Unit: 1633

Figure 2 Diagram and nucleotide sequence of the pClip ribozyme cassette.

Figure 3 Diagram and nucleotide sequence of the pChop ribozyme cassette.

5 Figure 4 Schematic diagram of the pSnip ribozyme cassette. pSnip includes sequences of the pClip triple ribozyme cassette, catalytic core targeted ribozymes comprising two linked trans-acting ribozymes, and sequences from the pChop triple ribozyme cassette

4. There is no support for any other pCLIP cassettes in the specification as filed, such that there is support for a *pCLIP* cassette other than the one disclosed in the specification as filed as Figure 2. Moreover, since applicants are relying upon the disclosure relies upon the incorporation by reference to an unpublished US application, and a foreign patent application as support for the claimed invention, this incorporation by reference is improper, as per the following:

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

As stated in the prior Office Action, the specification as filed does not specifically teach that the lengths of the first and second arms of the ribozyme construct of Figure 3 are actually longer than the corresponding arms of a pCLIP cassette. Although, applicants also disclose the lengthening of the carms of cis-acting ribozymes, at page 36, lines 7-8, there is no disclosure to support the particular lengthening of arms with respect to the binding arms of a pCLIP cassette. Moreover, the instant claims do not recite any particular length, or even the length of the arms of the pCLIP cassette, the claim merely recites wherein one of first and second arms are longer that the corresponding arms of a *pCLIP* cassette. As stated in the prior Office Action, Applicant's amendment is

Art Unit: 1633

considered new matter, since the scope of the added material claimed is not supported by the original disclosure. Applicant is required to cancel the new matter in the reply to this Office Action. See MPEP § 608.4(a) and §706.03(o).

5. Claims 1, 4-5, 7, 10, 12, 17, 19-24, 26, and 35-36, and 38 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Applicant's arguments filed 4-04-06 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that a person having ordinary skill in the art reading Applicant's specification would have had no problem understanding what this phrase means. Moreover, Applicants argue that this is particularly true given the plain meaning of the word "longer", and Figure 2 discloses a pCLIP cassette.

7. Contrary to Applicant's assertions, it is noted that the instant claims are not limited to wherein the pCLIP recited in the claims is actually the pCLIP cassette recited in Figure 2. Therefore, as stated in the prior Office Action, the claims are indefinite since the claims do not define what the lengths of the corresponding arms of a pCLIP cassette actually are, such that the ordinary skilled artisan would be immediately apprised of the scope of the claimed invention, in order to understand how to design ribozyme cassettes wherein "one of said first and second arms is proximal to said trans-acting ribozyme, and the other of said first and second arms is longer than the corresponding arm of a pCLIP cassette."

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1633

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 9:30 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 517-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Janet L. Epps-Ford
Examiner
Art Unit 1633

JLE